K061902

DEC - 8 2006

5. 510(k) Summary (21CFR § 807.92)

Submitted by: Inditherm Medical
Houndhill Park
Bolton Road
Rotherham S63 7LG
United Kingdom

Contact: Nick Bettles, Division Director – Medical

Establishment Registration Number: 3005246910

Date Prepared: June 30, 2006

Trade Name: Inditherm CosyTherm Neonatal Warming System
Model numbers: NCM1, NCM2, NCB1, CCU1, CRU1

Common Name: Thermal Regulating System

Device Classification: Thermal Regulating System 21 CFR 870.5900

Class: II

Product Code: DWJ

Classification Panel: Cardiovascular Therapeutic Devices

Equivalent Marketed Device: Inditherm Patient Warming System (K051419)

Device Description: The Inditherm CosyTherm system consists of a precision temperature control unit that controls and monitors the temperature of a mattress or blanket composed of a carbon polymer material. A pressure relief pad is integrated into the mattress, underneath the flexible warming surface.

Intended Use: Designed for use in the neonatal intensive care unit

	(NICU), Special Care Baby Unit (SCBU), delivery suite and post-natal wards, the CosyTherm system provides safe and controlled warming to assist newborn infants to maintain normal body temperature. In addition to providing warming, the mattress also includes a pressure relief pad. Contrast to Predicate: The predicate device is sized for and intended for use in adult and pediatric populations in the operating room, anaesthetic room, intensive care, emergency department, on medical and surgical wards and for patient transport.
Technological Characteristics:	The CosyTherm system uses the same technology as the predicate device; resistive carbon polymer technology. The CosyTherm predicate device has similar intended uses and has similar features which include: principle of operation, indications for use, safety standards compliance, thermal safety features, EMI compatibility and configurations
Non-Clinical Testing:	Inditherm conducted testing against recognized standards for electrical safety and electromagnetic emissions and immunity. Performance testing was also conducted to assure adequate temperature accuracy and stability as well as the proper functioning of thermal safety features. All test results verify the device meets or exceeds predetermined specifications.
Clinical Testing:	None submitted
Summary:	Based on Performance Testing results and specifications, the CosyTherm system is substantially equivalent to the Inditherm Patient Warming System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2006

Inditherm Medical
c/o Andy Anderson
5353 Wayzata Blvd. Suite 505
Minneapolis, MN 55416

Re: K061902
Trade/Device Name: Cosytherm Neonatal Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: II
Product Code: DWJ
Dated: November 16, 2006
Received: November 17, 2006

Dear Mr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-4080. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indication For Use Statement - K061902

Designed for use in the neonatal intensive care unit (NICU), Special Care Baby Unit (SCBU), delivery suite, post-natal wards and during transport, the CosyTherm warming system provides safe and controlled warming to assist newborn infants to maintain normal body temperature. In addition to providing warming, the mattress also includes a pressure relief pad.

Prescription Use ___X___ OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – (CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061902